

1 **MEDICATION GUIDE**

2 **REVLIMID** (rev-li-mid)

3 (lenalidomide)

4 Capsules

5 Read the Medication Guide that comes with REVLIMID before you start taking it and  
6 each time you get a new prescription. There may be new information. This Medication  
7 Guide does not take the place of talking to your healthcare provider about your medical  
8 condition or your treatment.

9 **What is the most important information I should know about REVLIMID?**

10 • Before you begin taking REVLIMID, you must read and agree to all of the  
11 instructions in the RevAssist program.

12 • REVLIMID may cause serious side effects including:

13 **Possible birth defects (deformed babies) or death of an unborn baby.** Females  
14 who are pregnant or who plan to become pregnant must not take REVLIMID.

15 **REVLIMID is similar to the medicine thalidomide (THALOMID).** We know  
16 thalidomide can cause severe life-threatening birth defects. REVLIMID has not been  
17 tested in pregnant women. REVLIMID has harmed unborn animals in animal testing.

18 **Females must not get pregnant:**

- 19 • for 4 weeks before starting REVLIMID  
20 • while taking REVLIMID  
21 • during any breaks (interruptions) in your treatment with REVLIMID  
22 • for 4 weeks after stopping REVLIMID

23 **If you become pregnant while taking REVLIMID, stop taking it right away and**  
24 **call your healthcare provider.** If your healthcare provider is not available, you can  
25 call 1-888-668-2528 for medical information. Healthcare providers and patients  
26 should report all cases of pregnancy to:

- 27 • FDA MedWatch at 1-800-FDA-1088, and  
28 • Celgene Corporation at 1-888-423-5436  
29

30 **It is not known if REVLIMID passes into semen, so:**

- 31 • Males, including those who have had a vasectomy, must use a latex condom  
32 during any sexual contact with a pregnant female or a female that can become  
33 pregnant while taking REVLIMID, during any breaks (interruptions) in your  
34 treatment with REVLIMID, and for 4 weeks after stopping REVLIMID. (If you or  
35 your partner are allergic to latex, please consult with your healthcare provider)  
36  
37  
38  
39 • Do not have unprotected sexual contact with a female who is or could become  
40 pregnant. Tell your healthcare provider if you do have unprotected sexual contact

41 with a female who is or could become pregnant.

42

- 43 • Do not donate sperm while taking REVLIMID, during any breaks (interruptions)
- 44 in your treatment, and for 4 weeks after stopping REVLIMID. If a female
- 45 becomes pregnant with your sperm, the baby may be exposed to REVLIMID and
- 46 may be born with birth defects.

47

48 **Men, if your female partner becomes pregnant, you should call your healthcare**

49 **provider right away.**

50 **Low white blood cells (neutropenia) and low platelets (thrombocytopenia).**

51 REVLIMID causes low white blood cells and low platelets in most patients. You may

52 need a blood transfusion or certain medicines if your blood counts drop too low. If

53 you are being treated for del 5q myelodysplastic syndromes (MDS) your blood counts

54 should be checked weekly during the first 8 weeks of treatment with REVLIMID, and

55 at least monthly thereafter. If you are being treated for multiple myeloma, your blood

56 counts should be checked every 2 weeks for the first 12 weeks and then at least

57 monthly thereafter.

58 **A higher chance for blood clots in your veins and lungs.** Call your healthcare

59 provider or get medical help right away if you get any of these signs or symptoms:

- 60 • shortness of breath
- 61 • chest pain
- 62 • arm or leg swelling

63

64 **What is REVLIMID?**

65 REVLIMID is a prescription medicine taken by mouth to treat certain patients who have

66 myelodysplastic syndromes (MDS). People with MDS have bone marrow that does not

67 produce enough mature blood cells. This causes a lack of healthy blood cells that can

68 function properly in the body. There are different types of MDS. REVLIMID is for the

69 type of MDS with a chromosome problem where part of chromosome 5 is missing. This

70 type of MDS is known as deletion 5q MDS. People with this type of MDS may have low

71 red blood cell counts that require treatment with blood transfusions.

72 REVLIMID is also used with dexamethasone to treat people with multiple myeloma who

73 have already had another treatment. Multiple myeloma is a cancer of plasma cells.

74 Plasma cells are found in the bone marrow. Normal plasma cells produce proteins called

75 antibodies. Some antibodies can attack and kill disease causing germs. People with

76 multiple myeloma may have low blood cell counts and immune problems giving them a

77 higher chance for getting infections such as pneumonia. They may also have bone pain and

78 breaks (fractures).

79 **Who should not take REVLIMID?**

- 80 • **Do not take REVLIMID if you are pregnant, plan to become pregnant, or**
- 81 **become pregnant during REVLIMID treatment.** See “What is the most important
- 82 information I should know about REVLIMID?”

- 83 • **Do not take REVLIMID if you are allergic to anything in it.** See the end of this  
84 Medication Guide for a complete list of ingredients in REVLIMID.

85 **What should I tell my healthcare provider before taking REVLIMID?**

86 Tell your healthcare provider about all of your medical conditions, including if you:

- 87 • **are pregnant or breastfeeding.** REVLIMID must not be used by women who are  
88 pregnant or breastfeeding. See “What is the most important information I should  
89 know about REVLIMID?” It is not known if REVLIMID passes into your breast milk  
90 and harms your baby.

91 **Tell your healthcare provider about all the medicines you take including**  
92 **prescription and non-prescription medicines, vitamins and herbal supplements.**  
93 REVLIMID and other medicines may affect each other causing serious side effects.

94 Know the medicines you take. Keep a list of them to show your healthcare provider and  
95 pharmacist.

96 **How should I take REVLIMID?**

97 Take REVLIMID exactly as prescribed and follow all the instructions of the RevAssist  
98 program. Before prescribing REVLIMID, your healthcare provider will:

- 99 • explain the RevAssist program to you  
100 • have you sign the Patient-Physician Agreement Form  
101 • Swallow REVLIMID capsules whole with water once a day. **Do not break, chew, or**  
102 **open your capsules.**  
103 • Do not open the REVLIMID capsules or handle them any more than needed. If you  
104 touch a broken REVLIMID capsule or the medicine in the capsule, wash the area of  
105 your body with soap and water.  
106 • If you miss a dose of REVLIMID, and it has been less than 12 hours since your  
107 regular time, take it as soon as you remember. If it has been more than 12 hours, just  
108 skip your missed dose. **Do not** take 2 doses at the same time.  
109 • If you take too much REVLIMID or overdose, call your healthcare provider or poison  
110 control center right away.

111 Females who can become pregnant:

- 112 • will have pregnancy tests weekly for 4 weeks, then every 4 weeks if your menstrual  
113 cycle is regular, or every 2 weeks if your menstrual cycle is irregular.  
114  
115 If you miss your period or have unusual bleeding, you will need to have a pregnancy  
116 test and receive counseling.  
117 • must agree to use 2 different forms of effective birth control at the same time, for 4  
118 weeks before, while taking, during any breaks (interruptions) in your treatment, and  
119 for 4 weeks after stopping REVLIMID.

120 Males who take REVLIMID, even those who have had a vasectomy, must agree to use a  
121 latex condom during sexual contact with a pregnant female or a female who can become  
122 pregnant. (If you or your partner is allergic to latex, please consult with your healthcare  
123 provider.)

#### 124 **What should I avoid while taking REVLIMID?**

- 125 • **Females: Do not get pregnant and do not breastfeed while taking REVLIMID.**  
126 **Males: Do not donate sperm,** See “What is the most important information I should  
127 know about REVLIMID?”, “Who should not take REVLIMID?”, and “What should I  
128 avoid while taking REVLIMID?”.
- 129 • **Do not share REVLIMID with other people.** It may cause birth defects and other  
130 serious problems.  
131
- 132 • **Do not donate blood** while you take REVLIMID, during any breaks (interruptions)  
133 in your treatment, and for 4 weeks after stopping REVLIMID. If someone who is  
134 pregnant gets your donated blood, her baby may be exposed to REVLIMID and may  
135 be born with birth defects.

#### 136 **What are the possible side effects of REVLIMID?**

- 137 • **REVLIMID may cause serious side effects.**  
138 • See “What is the most important information I should know about REVLIMID?”  
139
- 140 • **Serious skin reactions.** Serious skin reactions can happen with REVLIMID and may  
141 cause death. Call your healthcare provider right away if you have any skin reaction  
142 while taking REVLIMID.  
143
- 144 • **Tumor lysis syndrome.** Metabolic complications that can occur during treatment of  
145 cancer and sometimes even without treatment. These complications are caused by the  
146 breakdown products of dying cancer cells and may include the following: changes to  
147 blood chemistry, high potassium, phosphorus, uric acid, and low calcium  
148 consequently leading to changes in kidney function, heart beat, seizures, and  
149 sometimes death.

150 Common side effects of REVLIMID are:

- 151 • diarrhea
- 152 • itching
- 153 • rash
- 154 • tiredness

155 These are not all the possible side effects of REVLIMID. Tell your healthcare provider  
156 about any side effect that bothers you or that does not go away.

157 Call your healthcare provider for medical advice about side effects. You may report side  
158 effects to FDA at 1-800-FDA-1088.

159 **How should I store REVLIMID?**

- 160 • Store REVLIMID at room temperature, 59°F to 86°F (15°C to 30°C).

161 **Keep REVLIMID and all medicines out of the reach of children.**

162 **General information about REVLIMID**

163 Medicines are sometimes prescribed for purposes other than those listed in a Medication  
164 Guide. **Do not** take REVLIMID for conditions for which it was not prescribed. **Do not**  
165 give REVLIMID to other people, even if they have the same symptoms you have. It may  
166 harm them and may cause birth defects.

167 This Medication Guide provides a summary of the most important information about  
168 REVLIMID. If you would like more information, talk with your healthcare provider.  
169 You can ask your healthcare provider or pharmacist for information about REVLIMID  
170 that is written for healthcare professionals. You can also call 1-888-423-5436 or visit  
171 [www.REVLIMID.com](http://www.REVLIMID.com).

172 **What are the ingredients in REVLIMID?**

173 Active ingredient: lenalidomide

174 Inactive ingredients: lactose anhydrous, microcrystalline cellulose, croscarmellose  
175 sodium, and magnesium stearate.

176 The 5 mg and 25 mg capsule shells contain gelatin, titanium dioxide and black ink. The  
177 10 mg capsule shell contains gelatin, FD&C blue #2, yellow iron oxide, titanium dioxide  
178 and black ink. The 15 mg capsule shell contains gelatin, FD&C blue #2, titanium dioxide  
179 and black ink.

180 Manufactured for Celgene Corporation

181 Summit, NJ 07901

182 This Medication Guide has been approved by the US Food and Drug Administration.

183 RevPlyMG.00X XX/09

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